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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/569,710	03/08/2007	Daniel Jacobus Steenkamp	169-87441	7959

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FITCH EVEN TABIN AND FLANNERY
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CHICAGO, IL 60603-3406

EXAMINER

NWAONICHA, CHUKWUMA O

ART UNIT	PAPER NUMBER
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1621

MAIL DATE	DELIVERY MODE
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10/15/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/569,710

Applicant(s)

STEENKAMP, DANIEL JACOBUS

Examiner

Chukwuma O. Nwaonicha

Art Unit

1621

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
 - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
 - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 08 March 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-18 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-18 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Current Status

1. Claims 1-18 are pending in the application.

Priority

Acknowledgment is made of applicant's claim for foreign priority under 35 U.S.C. 119(a)-(d).

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-18 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 is rejected because the variable R is defined as "a non-immobilized hydrophobic moiety". It is not clear what moiety applicant is claiming, and the variable R' is not defined. Clarification is required.

Claim 6 is rejected because the variable R is defined as "a non-polar thiol". It is not clear what non-polar thiol applicant is claiming. Clarification is required.

Claim 16 is rejected because the variable R is defined as "a hydrophobic moiety". It is not clear what hydrophobic moiety applicant is claiming. Clarification is required.

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Claims 11 and 17 are rejected because the variable R is defined as "polynuclear aromatic group". It is not clear what polynuclear aromatic group applicant is claiming.

Clarification is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-18 provide for the method of reducing the purified disulphide, but, since the claim does not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a process without any active, positive steps delimiting how this use is actually practiced.

Claims 1-18 are rejected under 35 U.S.C. 101 because the claimed recitation of a method of reducing the purified disulphide, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd. v. Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

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(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim 1 is rejected under 35 U.S.C. 102(b) as being anticipated by Gutcho et al., {US 2,820,780}.

Gutcho et al. disclose applicants' claimed process of reducing disulphide and isolating the thiol. See columns 1-4.

Claims 16-18 are rejected under 35 U.S.C. 102(a) as being anticipated by Fahey et al., {US 6,780,418 same as WO 99/21580}

Fahey et al. disclose applicants claimed disulphide. Applicants have claimed a product by way of a product by process claim. The Examiner did not give any patentable weight to the process step.

Claims 16-18 are rejected under 35 U.S.C. 102(b) as being anticipated by Gutcho et al., {US 2,820,780}.

Gutcho et al. disclose applicants claimed disulphide. Applicants have claimed a product by way of a product by process claim. The Examiner did not give any patentable weight to the process step.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject

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matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148

USPQ 459 (1966), that are applied for establishing a background for determining

obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fahey et al., {US 6,780,418} in view of Gutcho et al., {US 2,820,780}.

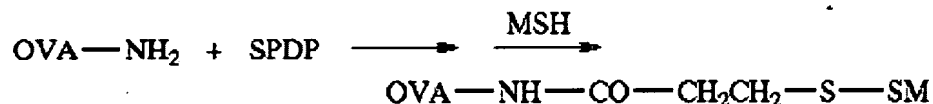
Applicants claim a method of isolating a thiol R'SH from a thiol-containing mixture, the method including the steps of forming a mixed disulphide R'SSR of the thiol R'SH in the mixture, in which R is a non-immobilised hydrophobic moiety; purifying the mixed disulphide R'SSR; reducing the purified mixed disulphide R'SSR to produce a mixture of thiols R'SH and RSH; and isolating the thiol R'SH; wherein all the other variables are as defined in the claims.

Determination of the scope and content of the prior art (M.P.E.P. §2141.01)

Fahey et al. teach a reversed phase HPLC process for separation of mycothiol and mycothiol disulphide. The process includes detecting mycothiol and mycothiol precursor in a bacterial colony. The process further includes biotinylating mycothiol and mycothiol precursor to form biotinylated mycothiol and biotinylated mycothiol precursor followed by formation of a complex, the complex was then detected.

Ascertainment of the difference between the prior art and the claims (M.P.E.P..**§2141.02)**

Fahey et al. process of isolation of a thiol differs from the instantly claimed process of isolating R'SH from a thiol containing mixture in that applicants' claim a process that purifies and isolate R'SH while Fahey et al. teach a process of detecting mycothiol in the form of disulphide. Another difference between applicants claimed invention and the teaching of Fahey et al. is that applicants' claim a process of forming a mixed disulphide R'SSR, followed by reduction of the purified mixed disulphide R'SSR to produce a mixture of thiols R'SH and RSH while Fahey et al. teach a process that isolated polyclonal antibody which binds to mycothiol as shown by the reaction below. Fahey et al. is silent about the reduction of the disulphide.



However, the secondary reference of Gutcho et al. teaches a process of reducing disulphide. See columns 1-4.

Finding of prima facie obviousness--rational and motivation (M.P.E.P.. §2142-**2143)**

The instantly claimed method of isolating a thiol R'SH from a thiol-containing mixture would have been suggested to one of ordinary skill because one of ordinary skill wishing to obtain pure thiol from a thiol-containing mixture is taught to employ the process of Fahey et al. and Gutcho et al.

One of ordinary skill in the art would have a reasonable expectation of success in practicing the instant invention by varying the process conditions from the teachings of Fahey et al. and Gutcho et al. to arrive at the instantly claimed process of isolating a thiol R'SH from a thiol-containing mixture. Said person would have been motivated to practice the teachings of the references cited because they demonstrate that thiols have some advantages and disadvantages in medical field. The instantly claimed invention would therefore have been obvious to one of ordinary skill in the art.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Chukwuma O. Nwaonicha whose telephone number is 571-272-2908. The examiner can normally be reached on Monday thru Friday, 8:30am to 5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne (Bonnie) Eyler can be reached on 571-272-0871. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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Chukwuma O. Nwaonicha, Ph.D.
Patent Examiner
Art Unit: 1621

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